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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,954	05/22/2006	David Hugh Jones	KIST0101PUSA	9624

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EXAMINER	
NOAKES, SUZANNE MARIE	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/595,954	JONES, DAVID HUGH	
	Examiner	Art Unit	
	SUZANNE M. NOAKES	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 24-42* is/are pending in the application.

4a) Of the above claim(s) *22 and 24-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. The amendments to the claims, specification and abstract filed 09 October 2008 is acknowledged. Claims 1-22 and 24-42 are pending, claims 22 and 24-42 remain withdrawn from further consideration for being drawn to non-elected subject matter and claims 1-21 are subject to examination on the merits.

Withdrawal of Previous Objections/Rejections

2. Any objection or rejection recited in the previous Office action and not explicitly restated below is hereby withdrawn.

3. The objection to the arrangement to the specification is withdrawn in view of Applicants amendments to the specification.

4. The objection to claims 6 and 14 for reciting acronyms without further details is withdrawn in view of the amendments to said claims.

5. The rejection of claims 1-21 under 35 U.S.C. 112 2nd paragraph for the omission of essential method steps is withdrawn in view of the amendments to claims 1.

6. The rejection of claim 14 under 35 U.S.C. 112 2nd paragraph for lacking antecedent basis is withdrawn in view Applicants arguments.

7. The rejection of claims 1-21 under 35 U.S.C. 112 1st paragraph, scope of enablement, is withdrawn in view of Applicants amendments to the claims which limits the protein to ConA.

New Rejections – Necessitated by Amendments

Claim Objections

8. Claim 1 is objected to because of the following grammatical informality: In the second line of said claim 1, the phrase "…..protein expressed in a bacterial host cells…." would read more accurately as "……protein expressed in bacterial host cells…." Or alternatively, "…..a protein expressed in a bacterial host cell….".

9. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21, which is dependent upon claim 20, recites that the glucose binding protein is Concanavalin A; however claim 1 has been amended to recite that the method produces Concanavalin A *only*.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 2nd paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 15-19 recites the limitation "A method as claimed in claim 1 wherein said non-plant host cell…."" in reference to claim 1. There is insufficient antecedent basis for this limitation in the claims because claim 1 has been amended to recite only bacterial host cells and has removed the phrase "non-plant host cell".

12. Claims 20-21 recites the limitation "A method as claimed in claim 1 wherein said glucose binding protein…."" in reference to claim 1. There is insufficient antecedent basis for this limitation in the claims because claim 1 has been amended to recite a method of obtaining *only* Concanavalin A.

Claim Rejections - 35 USC § 112 – 2nd paragraph

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 2-13 are deemed indefinite. Claim 2 has been amended to recite "adding a buffer, in which glycogen is soluble but in which Concanvalin A is insoluble, to the lysate" because it is unclear in claim 2 whether or not the buffer which is being added contains soluble glycogen and insoluble ConA (which is how the claim reads but which does not make much sense).

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1-3, 4, 14-16, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Min et al. (EMBO J., 1992, 11(4):1303-1307 – cited on IDS from 28 July 2006).

The instant specification states that glycogen synthesized in bacterial cells forms a complex with *active conconavalin A* (ConA) – (see p. 7, last paragraph, to p. 8, 1st paragraph) and that *E. coli* produces significant amounts of glycogen, especially when the growth medium is supplemented with the carbon source glucose.

Min et al. teach the expression of active recombinant pro-ConA in *E. coli* cultured in M9 medium (supplemented with 0.5% (w/v) cas-amino acids, 4 mg/ml glucose, 2 μg/ml, 300 μg/ml glutamic acid, 40 μg/ml uracil and μg/ml ampicillen) (see p. 1306, second column, Growth Induction and Lysis of Cells). The cultures were centrifuged and then lysed in 20 mM MOPS-metal buffer, 1 mM $CaCl_2$, 1 mM $MnCl_2$ p.H 7.0, and sonicated. The lysate placed on ice for one hour and centrifuged. The protein ConA appeared in the pellet and was thus removed from the lysate – the pellet was subsequently resuspsended in denaturing buffer and spun over night and diluted several fold before being purified in an active recombinant form by affinity chromatography (see p. 1306, 2nd column, Materials and Methods). As it is noted above and in Applicants remarks ("The teaching of Dincturk isn't even relevant to the present invention, as the precipitation of pre-pro-ConA does not encounter the same problems as *the precipitation of active ConA (namely, complexing with glycogen).*" – see Remarks, p. 19, 3rd paragraph), active ConA forms a complex with glycogen, and thus when Min et al. teach removing the precipitated ConA by centrifuging the cell lysate, inherently the

glycogen-ConA complex is thus removed as well. Therefore, the glycogen content of the cell lysate is also being reduced at the same time. Since claim 1 simply states the method of obtaining a recombinant active ConA is achieved by reducing the glycogen content of a cell lysate, the teachings of Min et al. meets this limitation because even those the ConA is pro-ConA, said protein clearly is active (see p. 1305, discussion and Abstract). With regard to claims 2 and 3, the claims do not require that the protein be insoluble as a direct consequence of "treating" the lysate with the buffer. Thus, the fact that protein is insoluble already (whether it has to do to the fact that glycogen complexes to it and makes it insoluble or other factors that make expressing eukaryotic proteins in prokaryotes difficult and form inclusion bodies, is inconsequential), the excess glycogen and at least some of the other impurities would be soluble in the buffer as taught by Min et al.

Response to Arguments

17. Applicant's arguments with respect to claims 1-3, 14-16, 20 and 21 as being anticipated by Dincturk et al. have been considered but are moot in view of the new ground(s) of rejection.

Nonetheless, the arguments as they apply to Min et al. will be addressed as many of the noted arguments/deficiencies noted by Applicants *may apply* to Min et al.

Applicants argue that

> "In addition, Dincturk fails to teach or suggest the step of "producing a lysate ... wherein the lysate has a reduced glycogen content." Dincturk as a whole teaches the generation of a particular recombinant pre-pro-Con A product that is low in solubility (Title and page 638). It is further contemplated that the low solubility of

> pre-pro-Con A is due to the presence of a plant signal peptide (page 638). In fact, Dincturk entirely fails to mention the word "glycogen", let alone producing a lysate with reduced glycogen content as recited in the independent claim 1."

In the context of Min et al., however, this argument will not be relevant because clearly the protein is grown in the presence of assimilatable carbon source, e.g. glucose which gets metabolized to glycogen, and thus by the very fact and nature that Applicants claims recognize this as such (see claims 18 and 19) and that Applicants arguments state specifically that a glycogen-Con A complex is formed when said ConA is active (see arguments p. 19, paragraph 4), then a glycogen-ConA complex inherently forms. As there would be excess glycogen in the lysate, removing the ConA-glycogen complex by centrifuging thus *does* reduce the glycogen content. The claims require no particular method to remove the glycogen or any particular amount to be removed/reduced.

Applicants also argue the following (last paragraph p. 19 to first of p. 20)

> "The very discovery leading to the present invention, namely the discovery of reducing glycogen content and recovering Con A using a buffer which differentiates the Con A from its surrounding impurities such as glycogen, may not be applied to supplement the deficiencies of Dincturk in order to render the present claims anticipated or obvious. Moreover, and contrary to what is stated in paragraph 13 of the Office Action, Dincturk does not teach or suggest the step of recovering Con A as recited in claim 1. Rather, as squarely acknowledged by the Examiner, Con A is removed together with glycogen if ever present, in the form of glycogen-Con A complex."

Applicants argue that the instant invention of reducing the glyogen content and recovering recombinant ConA by using a specifif buffer which will reduce the glycogen content is acknowledged, however, until such limitation is actually in the claims, the argument is irrelevant because the methods of reducing said glycogen from the lysate is not limited in the claims. With regard to recovering the ConA which is recited in claim 1,

Applicants are giving the claim limitation a very narrow interpretation; however, given broad, but reasonable, interpretation of recovering ConA, this can be nothing more than leaving the ConA in the pellet after spinning it down from the cell lysate. There are no limitations whatsoever about what state the ConA has to be in at the end (e.g. purified). Nonetheless, Min et al. do teach purifying to a relative high purity, the recombinant active ConA.

Conclusion

18. No claim is allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
16 January 2008